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EXAMINER	
ZHENG, LI	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,793	VANCANNEYT ET AL.	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-18,20-28 and 30* is/are pending in the application.

4a) Of the above claim(s) *8,9,22,23,25,26 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-18,20,21,24,27 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6, 8-18, 20-28 and 30 are pending.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-17, 24, 27 and 29-30, including SEQ ID NO: 1, and cancellation of claims 7, 19 and 29 in the reply filed on 7/2/2007 is acknowledged (response, page 11, 2nd paragraph). Applicants traverse the restriction requirements between Groups I and II.

However, the restriction requirements between Groups I and II is withdrawn due to claim amendment.

Applicants are advised that since the restrictions between Groups I and II are withdrawn, if any claim(s) that include(s) the limitation of the examined claims is/are presented in a continuation or divisional application, the claim of the application may be subject to a provisional statutory and/or nonstatutory double patenting rejection over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 no longer apply. MPEP804.01.

Claims 8-9, 22-23, 25-26 and 28 are withdrawn because they are drawn to non-elected invention groups or nucleotide sequences.

Claims 1-6, 10-18, 20-21, 24, 27, and 30 including SEQ ID NO: 1 are examined on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The specification is objected to under 37 CFR 1.821(d) as failing to refer to a sequence by use of its sequence identifier preceded by "SEQ ID NO:". For example, the nucleotide sequences in Figure 1 should be identified by SEQ ID NOs:. Alternatively, the brief description of the figure on page 8 can be amended to recite the identifiers.

Claim Objections

4. Claims 4-6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 1 recite a limitation that said first RNA region has about 94% sequence identity to the nucleotide sequence of said endogenous gene, however, the dependent claims 4-6 recites limitations that do not encompassed by the limitation of claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6, 10-18, 20-21, 24, 27, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation, "an oilseed rape", renders the claim indefinite. The definition is found in paragraph [00054]. However, it is unclear what else is also included. The metes and bounds are not clear.

In claims 1 and 10, the recitation, "homologous gene", render the claims indefinite. It is unclear what the recitation encompasses. What is considered to be a homologous gene. The metes and bounds are not clear.

In claims 1, 10, 12 and 18, the recitation, "an *INDEHISCENT* gene from Arabidopsis thaliana", renders the claims indefinite. The sole designation of a nucleotide sequence by "an *INDEHISCENT* gene from Arabidopsis thaliana" is arbitrary and creates ambiguity in the claims. For example, the nucleotide sequence in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different nucleotide sequence. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F .2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection.

Claim 1 recites the limitation "said 19 consecutive nucleotides" in part (ii) and (iii). There is insufficient antecedent basis for this limitation in the claim. It is suggested to replace it with – said at least 19 consecutive nucleotides --.

In claim 1, the selection step only involves selecting plant exhibiting reduced seed shattering. However, according to the claim, "maintaining an agronomically relevant threshability" is also essential for the method. Therefore, the selection step also should include selecting plants with such feature.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-6, 10-18, 20-21, 24, 27, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a gene silencing method involves a nucleotide sequence of at least 19 consecutive nucleotides having about 94% sequence identity to an

endogenous homologous gene of *INDEHISCENT* gene in oilseed rape plant; or a nucleotide sequence of about 19 to about 500 consecutive nucleotides having a sequence similarity of about 90% to about 100% to said endogenous gene; or a nucleotide sequence of about 50 to about 500 consecutive nucleotides having a sequence similarity of about 50% to about 88% to said endogenous gene; or a nucleotide sequence of about 200 to about 300 consecutive nucleotides having a sequence similarity of about 65% to about 75% to said endogenous gene; or a nucleotide sequence comprising at least 19 consecutive nucleotides from SEQ ID NO: 1; or a nucleotide sequence comprising at least 50 or 100 consecutive nucleotides having at least about 90% sequence identity to SEQ ID NO: 1.

The specification teach a dsRNA encoding gene silencing vector including sense and antisense fragment of a 211 bp fragment from nucleotides 27-239 of SEQ ID NO: 1 (specification, page 22, lines 4-27). The specification also teaches two homologous genes of SEQ ID NO: 1 from Brassica napus, named as BN1 and BN2 (Figure 1; also page 24, line 1 to page 26, line 3).

The Applicants do not describe any polynucleotide sequence that has at least 19 consecutive nucleotides having about 94% sequence identity to a homologous gene of *INDEHISCENT* gene from Arabidopsis thaliana in oilseed rape plant; or any nucleotide sequence of about 19 to about 500 consecutive nucleotides having a sequence similarity of about 90% to about 100% to said endogenous gene; or any nucleotide sequence of about 50 to about 500 consecutive nucleotides having a sequence similarity of about 50% to about 88% to said endogenous gene; or any nucleotide

sequence of about 200 to about 300 consecutive nucleotides having a sequence similarity of about 65% to about 75% to said endogenous gene; or any nucleotide sequence comprising at least 19 consecutive nucleotides from SEQ ID NO: 1; or any nucleotide sequence comprising at least 50 or 100 consecutive nucleotides having at least about 90% sequence identity to SEQ ID NO: 1, except for a 211 bp fragment from nucleotides 27-239 of SEQ ID NO: 1. The only dsRNA vector that confers podshatter resistance to Brassica napus while maintaining an agronomically relevant threshability is pTCO219, which includes sense and antisense fragments of a 211 bp fragment from nucleotides 27-239 of SEQ ID NO: 1. Further, the only described homologous genes of *INDEHISCENT* in oilseed rape plant are BN1 and BN2 from Brassica napus.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial

portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences falling within the scope of the claimed genus nucleotide sequences of at least 19 consecutive nucleotides having about 94% sequence identity to a homologous gene of *INDEHISCENT* gene from Arabidopsis thaliana (SEQ ID NO: 1) in oilseed rape plant; or a nucleotide sequence of about 50 to about 500 consecutive nucleotides having a sequence similarity of about 50% to about 88% to said endogenous gene. Applicants only describe gene silencing structure that contains an inverted repeat of a 211 bp fragment from nucleotides 27-239 of SEQ ID NO: 1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Since said genus has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

8. Claims 1-6, 10-18, 20-21, 24, 27, and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for reducing seed shattering in an Brassica napus plant while maintaining an agronomically relevant

threshability by expressing a gene silencing cassette containing an inverted repeat of a 211 bp fragment from nucleotides 27-239 of SEQ ID NO: 1 driven by CaMV 35S promoter, does not reasonably provide enablement for a method for any oilseed rape plant by expressing any other gene silencing cassette. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The instant claims are drawn to a method for reducing seed shattering in an oilseed rape plant while maintaining an agronomically relevant threshability by expressing a recombinant expression cassette comprising a promoter operably linked to an inverted repeat of a nucleotide sequence comprising at least 19 consecutive nucleotides having about 94% sequence identity to an endogenous homologous gene of *INDEHISCENT* gene (SEQ ID NO: 1) in oilseed rape plant; or a nucleotide sequence of about 19 to about 500 consecutive nucleotides having a sequence similarity of about 90% to about 100% to said endogenous gene; or a nucleotide sequence of about 50 to

about 500 consecutive nucleotides having a sequence similarity of about 50% to about 88% to said endogenous gene; or a nucleotide sequence of about 200 to about 300 consecutive nucleotides having a sequence similarity of about 65% to about 75% to said endogenous gene; or a nucleotide sequence comprising at least 19 consecutive nucleotides from SEQ ID NO: 1; or a nucleotide sequence comprising at least 50 or 100 consecutive nucleotides having at least about 90% sequence identity to SEQ ID NO: 1.

The specification teach a method for reducing seed shattering in an Brassica napus plant while maintaining an agronomically relevant threshability by expressing dsRNA encoding gene silencing vector, pTCO219, including sense and antisense fragment of a 211 bp fragment from nucleotides 27-239 of SEQ ID NO: 1 under the control of CaMV 35S promoter (specification, page 22, lines 4-27). The specification also teaches two homologous genes of SEQ ID NO: 1 from Brassica napus, named as BN1 and BN2 (Figure 1; also page 24, line 1 to page 26, line 3).

To practice the instant invention, a person with ordinary skill in the art is required to transform a gene silencing vector expressing dsRNA to partially suppress the endogenous homologous gene of *INDEHISCENT* gene to a certain extend so that seed shattering in an oilseed rape plants is reduced while an agronomically relevant threshability is maintained. However, Applicant only provide guidance on how to achieve the goal by using a dsRNA encoding gene silencing vector, pTCO219, including sense and antisense fragment of a 211 bp fragment from nucleotides 27-239 of SEQ ID NO: 1 under the control of CaMV 35S promoter. Applicants have not taught how one

skilled in the art can use other the claimed sequences to generate an oilseed rape plant with reduced seed shattering while maintaining an agronomically relevant threshability.

The specification teaches that the sequence homology affects the outcome of the claimed method. For example, a similar construct using two homologous genes of SEQ ID NO: 1 from Brassica napus failed to exhibit any meaningful RIT which is the measurement for agronomically relevant threshability (paragraph [000107]-[000109]).

The specification also shows that promoter activity affects the outcome of the claimed method (page 32, Table 1).

It is unclear the pTCO219 would work similarly in other oilseed rape plants as in Brassica napus since the specification does not teach any homologous genes of NDEHISCENT in other oilseed rape plants that might be suppressed.

Applicants claimed phenotype requires a partial silencing of the endogenous gene. However, Applicants have not taught which combinations of strength of promoter, homology of sequence and length of the sequence will yield the desirable result.

Further, Thomas et al. (2001, *The Plant Journal* 25(4):417-425) teach that the lower size limit required for targeting reporter transgene mRNA de novo using PTGS was 23 nucleotides of complete identity, a size corresponding to that of small RNAs associated with PTGS in plant and RNAi in animals. Therefore, all of the DNA segments smaller than 23 nucleotides in instant claims are not enabled for silencing a target gene.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to design and produce multitude of non-

exemplified sequences by, for example, using site specific mutagenesis or making synthetic fragment, to isolate the resultant variants, to produce dsRNA expression vectors and transform plants therewith, as well as to identify those, if any, that when expressed would suppress the expression of the unknown homologous genes in oilseed rape plants so that seed shattering in an oilseed rape plants is reduced while an agronomically relevant threshability is maintained. See *Genentech Inc. v. Novo Nordisk,* A/S (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Therefore, given the claim breadth, lack of further guidance and additional working example, unpredictability of the art, undue experimentation would be required for a person skilled in the art to practice the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6, 10-18, 20-21, 24, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanofsky et al. (2006, U.S. Patent No. 7,135,621) in view Smith et al. (2000, *Nature*, 407:319-320).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are drawn to a method for reducing seed shattering in an oilseed rape plant while maintaining an agronomically relevant threshability by expressing a recombinant expression cassette comprising a promoter operably linked to an inverted repeat of a nucleotide sequence comprising at least 19 consecutive nucleotides having about 94% sequence identity to an endogenous homologous gene

of *INDEHISCENT* gene in oilseed rape plant; or a nucleotide sequence of about 19 to about 500 consecutive nucleotides having a sequence similarity of about 90% to about 100% to said endogenous gene; or a nucleotide sequence of about 50 to about 500 consecutive nucleotides having a sequence similarity of about 50% to about 88% to said endogenous gene; or a nucleotide sequence of about 200 to about 300 consecutive nucleotides having a sequence similarity of about 65% to about 75% to said endogenous gene; or a nucleotide sequence comprising at least 19 consecutive nucleotides from SEQ ID NO: 1; or a nucleotide sequence comprising at least 50 or 100 consecutive nucleotides having at least about 90% sequence identity to SEQ ID NO: 1.

The Office contend that the percentage identity to the homologous genes of *INDEHISCENT* gene (SEQ ID NO: 1) in oilseed rape plant is not given any patentable weigh due to the indefiniteness of "homologous genes of *INDEHISCENT* gene" (see rejection under 35 U.S.C. 112 second paragraph).

Yanofsky et al. teach a method of selecting a Brassica plant with delayed fruit dehiscence, the method comprising the steps of, (a) introducing into plants a recombinant expression cassette comprising a promoter operably linked to an antisense nucleotide sequence of nucleotides 2765-3361 of SEQ ID NO: 1, which represents the coding region of Arabidopsis *INDEHISCENT* gene; (b) identify plants in which the expression of *INDEHISCENT* homologous genes are suppressed; and (c) selecting a plant with delayed fruit dehiscence (claims 20-28). Yanofsky et al. also teach the Brassica plants comprising a recombinant expression cassette comprising a promoter operably linked to an antisense nucleotide sequence of nucleotides 2765-3361 of SEQ

ID NO: 1 (claims 6-17). Yanofsky further teach that the promoter is a dehiscence zone specific promoter (claim 5).

Yanofsky et al. do not teach a recombinant expression cassette comprising a promoter operably linked to an inverted repeat. Yanofsky et al. do not teach that the hairpin region formed by the inverted repeat is about 19 or 50 to about 500 consecutive nucleotides. Yanofsky et al. do not teach a relative weak plant expressible promoter. Yanofsky et al. do not teach that an agronomically relevant threshability should be maintained by the pods of transgenic plant. Yanofsky et al. do not teach Brassica plant being oilseed rape plant.

Smith et al. teach that a DNA construct that produces hairpin loop type of dsRNA (hpRNA) with functional (i.e. spiceable) intron as spacer enhances silencing efficiency (last two paragraph on left col. of page 320, and also figure 1). Smith et al. also teach that the modifications that help to align the complementary arms of the hairpin and promote the formation of a duplex could increase the efficiency of gene silencing (see last paragraph on the left column of page 320).

Given the recognition of those of ordinary skill in the art of the value of the method for reducing seed shattering in Brassica plants of Yanofsky et al., it would have been obvious for a person with ordinary skill in the art to modify gene silencing vector of Yanofsky et al. by replacing the antisense fragment with an inverted repeat structure according to the teaching of Smith et al. One skilled in the art would have been motivated to do so given the teaching of Smith et al. that the modifications increase the efficiency of gene silencing compared to antisense construct (Figure 1).

Although Yanofsky et al. do not teach a relative weak plant expressible promoter, the Office interprets dehiscence zone specific promoter of Yanofsky et al. to be a relative weak plant expressible promoter according to Applicants' definition of "a relative weak plant expressible promoter" (the specification, paragraph [00042]).

Although Yanofsky et al. do not teach Brassica plant being oilseed rape plant, according paragraph [00054] of the specification, oilseed rape plant includes Brassica napus, Brassica junceae and Brassica campestris. These three species represent half of six major Brassica species of economic importance (paragraph [0090] of U.S. Patent No. 7,135,621). Therefore oilseed rape plants are regarded as obvious species of Brassica plants.

Although Yanofsky et al. do not teach that the hairpin region formed by the inverted repeat is about 19 or 50 to about 500, or about 200 to about 300 consecutive nucleotides. However, those variants are considered as being obvious design choice.

Although Yanofsky et al. do not teach that an agronomically relevant threshability should be maintained by the pods of transgenic plant, such feature is obviously exhibited by the transgenic plant produced by the modified method.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

10. Claims 1-6, 10-18, 20-21, 24, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liljegren et al. (2006, U.S. Patent No. 6,998,517) in view Smith et al. (2000, *Nature*, 407:319-320).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant claims are discussed as above.

Liljegren et al. teach a method of selecting a Brassica plant with delayed fruit dehiscence, the method comprising the steps of, (a) introducing into plants a recombinant expression cassette comprising a heterologous promoter operably linked to an antisense nucleotide sequence of nucleotides 2765-3361 of SEQ ID NO: 1, which

represents the coding region of Arabidopsis *INDEHISCENT* gene; (b) identify plants in which the expression of *INDEHISCENT* homologous genes are suppressed; and (c) selecting a plant with delayed fruit dehiscence (claims 31-39). Liljegren et al. also teach the Brassica plants comprising a recombinant expression cassette comprising a heterologous promoter operably linked to an antisense nucleotide sequence of nucleotides 2765-3361 of SEQ ID NO: 1 (claims 29-30). Liljegren further teach that the promoter is a dehiscence zone specific promoter (claim 38).

Liljegren et al. do not teach a recombinant expression cassette comprising a promoter operably linked to an inverted repeat. Liljegren et al. do not teach that the hairpin region formed by the inverted repeat is about 19 or 50 to about 500 or about 200 to about 300 consecutive nucleotides. Liljegren et al. do not teach a relative weak plant expressible promoter. Liljegren et al. do not teach that an agronomically relevant threshability should be maintained by the pods of transgenic plant. Liljegren et al. do not teach Brassica plant being oilseed rape plant.

Smith et al. teach that a DNA construct that produces hairpin loop type of dsRNA (hpRNA) with functional (i.e. spiceable) intron as spacer enhances silencing efficiency (last two paragraph on left col. of page 320, and also figure 1). Smith et al. also teach that the modifications that help to align the complementary arms of the hairpin and promote the formation of a duplex could increase the efficiency of gene silencing (see last paragraph on the left column of page 320).

Given the recognition of those of ordinary skill in the art of the value of the method for reducing seed shattering in Brassica plants of Liljegren et al., it would have

been obvious for a person with ordinary skill in the art to modify gene silencing vector of Liljegren et al. by replacing the antisense fragment with an inverted repeat structure according to the teaching of Smith et al. One skilled in the art would have been motivated to do so given the teaching of Smith et al. that the modifications increase the efficiency of gene silencing compared to antisense construct (Figure 1).

Although Liljegren et al. do not teach a relative weak plant expressible promoter, the Office interprets dehiscence zone specific promoter of Liljegren et al. to be a relative weak plant expressible promoter according to Applicants' definition of "a relative weak plant expressible promoter" (the specification, paragraph [00042]).

Although Liljegren et al. do not teach Brassica plant being oilseed rape plant, according paragraph [00054] of the specification, oilseed rape plant includes Brassica napus, Brassica junceae and Brassica campestris. These three species represent half of six major Brassica species of economic importance (paragraph [0090] of U.S. Patent No. 7,135,621). Therefore oilseed rape plants are regarded as obvious species of Brassica plants.

Although Liljegren et al. do not teach that the hairpin region formed by the inverted repeat is about 19 or 50 to about 500 or about 200 to about 300 consecutive nucleotides. However, those variants are considered as being obvious design choice.

Although Liljegren et al et al. do not teach that an agronomically relevant threshability should be maintained by the pods of transgenic plant, such feature is obviously exhibited by the transgenic plant produced by the modified method.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-6, 10-18, 20-21, 24, 27, and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-39 of U.S. Patent No. 6,998,517 (hereafter "Liljegren et al.") in view Smith et al. (2000, *Nature*, 407:319-320).

The instant claims are drawn to a method for reducing seed shattering in an oilseed rape plant while maintaining an agronomically relevant threshability by

expressing a recombinant expression cassette comprising a promoter operably linked to an inverted repeat of a nucleotide sequence comprising at least 19 consecutive nucleotides having about 94% sequence identity to an endogenous homologous gene of *INDEHISCENT* gene in oilseed rape plant; or a nucleotide sequence of about 19 to about 500 consecutive nucleotides having a sequence similarity of about 90% to about 100% to said endogenous gene; or a nucleotide sequence of about 50 to about 500 consecutive nucleotides having a sequence similarity of about 50% to about 88% to said endogenous gene; or a nucleotide sequence of about 200 to about 300 consecutive nucleotides having a sequence similarity of about 65% to about 75% to said endogenous gene; or a nucleotide sequence comprising at least 19 consecutive nucleotides from SEQ ID NO: 1; or a nucleotide sequence comprising at least 50 or 100 consecutive nucleotides having at least about 90% sequence identity to SEQ ID NO: 1.

The Office contend that the percentage identity to the homologous genes of *INDEHISCENT* gene (SEQ ID NO: 1) in oilseed rape plant is not given any patentable weigh due to the indefiniteness of "homologous genes of *INDEHISCENT* gene" (see rejection under 35 U.S.C. 112 second paragraph).

Liljegren et al. teach a method of selecting a Brassica plant with delayed fruit dehiscence, the method comprising the steps of, (a) introducing into plants a recombinant expression cassette comprising a heterologous promoter operably linked to an antisense nucleotide sequence of nucleotides 2765-3361 of SEQ ID NO: 1, which represents the coding region of Arabidopsis *INDEHISCENT* gene; (b) identify plants in which the expression of *INDEHISCENT* homologous genes are suppressed; and (c)

selecting a plant with delayed fruit dehiscence (claims 31-39). Liljegren et al. also teach the Brassica plants comprising a recombinant expression cassette comprising a heterologous promoter operably linked to an antisense nucleotide sequence of nucleotides 2765-3361 of SEQ ID NO: 1 (claims 29-30). Liljegren further teach that the promoter is a dehiscence zone specific promoter (claim 38).

Liljegren et al. do not teach a recombinant expression cassette comprising a promoter operably linked to an inverted repeat. Liljegren et al. do not teach that the hairpin region formed by the inverted repeat is about 19 or 50 to about 500 or about 200 to about 300 consecutive nucleotides. Liljegren et al. do not teach a relative weak plant expressible promoter. Liljegren et al. do not teach that an agronomically relevant threshability should be maintained by the pods of transgenic plant. Liljegren et al. do not teach Brassica plant being oilseed rape plant.

Smith et al. teach that a DNA construct that produces hairpin loop type of dsRNA (hpRNA) with functional (i.e. spiceable) intron as spacer enhances silencing efficiency (last two paragraph on left col. of page 320, and also figure 1). Smith et al. also teach that the modifications that help to align the complementary arms of the hairpin and promote the formation of a duplex could increase the efficiency of gene silencing (see last paragraph on the left column of page 320).

Given the recognition of those of ordinary skill in the art of the value of the method for reducing seed shattering in Brassica plants of Liljegren et al., it would have been obvious for a person with ordinary skill in the art to modify gene silencing vector of Liljegren et al. by replacing the antisense fragment with an inverted repeat structure

according to the teaching of Smith et al. One skilled in the art would have been motivated to do so given the teaching of Smith et al. that the modifications increase the efficiency of gene silencing compared to antisense construct (Figure 1).

Although Liljegren et al. do not teach a relative weak plant expressible promoter, the Office interprets dehiscence zone specific promoter of Liljegren et al. to be a relative weak plant expressible promoter according to Applicants' definition of "a relative weak plant expressible promoter" (the specification, paragraph [00042]).

Although Liljegren et al. do not teach Brassica plant being oilseed rape plant, according paragraph [00054] of the specification, oilseed rape plant includes Brassica napus, Brassica junceae and Brassica campestris. These three species represent half of six major Brassica species of economic importance (paragraph [0090] of U.S. Patent No. 7,135,621). Therefore oilseed rape plants are regarded as obvious species of Brassica plants.

Although Liljegren et al. do not teach that the hairpin region formed by the inverted repeat is about 19 or 50 to about 500 or about 200 to about 300 consecutive nucleotides. However, those variants are considered as being obvious design choice.

Although Liljegren et al et al. do not teach that an agronomically relevant threshability should be maintained by the pods of transgenic plant, such feature is obviously exhibited by the transgenic plant produced by the modified method.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

12. Claims 1-6, 10-18, 20-21, 24, 27, and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-28 of U.S. Patent No. 7,135,621 (hereafter "Yanofsky et al.") in view Smith et al. (2000, *Nature*, 407:319-320).

The instant claims are discussed as above.

Yanofsky et al. teach a method of selecting a Brassica plant with delayed fruit dehiscence, the method comprising the steps of, (a) introducing into plants a recombinant expression cassette comprising a promoter operably linked to an antisense nucleotide sequence of nucleotides 2765-3361 of SEQ ID NO: 1, which represents the coding region of Arabidopsis *INDEHISCENT* gene; (b) identify plants in which the expression of *INDEHISCENT* homologous genes are suppressed; and (c) selecting a plant with delayed fruit dehiscence (claims 20-28). Yanofsky et al. also teach the Brassica plants comprising a recombinant expression cassette comprising a promoter operably linked to an antisense nucleotide sequence of nucleotides 2765-3361 of SEQ ID NO: 1 (claims 6-17). Yanofsky further teach that the promoter is a dehiscence zone specific promoter (claim 5).

Yanofsky et al. do not teach a recombinant expression cassette comprising a promoter operably linked to an inverted repeat. Yanofsky et al. do not teach that the hairpin region formed by the inverted repeat is about 19 or 50 to about 500 or about 200 to about 300 consecutive nucleotides. Yanofsky et al. do not teach a relative weak

plant expressible promoter. Yanofsky et al. do not teach that an agronomically relevant threshability should be maintained by the pods of transgenic plant. Yanofsky et al. do not teach Brassica plant being oilseed rape plant.

Smith et al. teach that a DNA construct that produces hairpin loop type of dsRNA (hpRNA) with functional (i.e. spiceable) intron as spacer enhances silencing efficiency (last two paragraph on left col. of page 320, and also figure 1). Smith et al. also teach that the modifications that help to align the complementary arms of the hairpin and promote the formation of a duplex could increase the efficiency of gene silencing (see last paragraph on the left column of page 320).

Given the recognition of those of ordinary skill in the art of the value of the method for reducing seed shattering in Brassica plants of Yanofsky et al., it would have been obvious for a person with ordinary skill in the art to modify gene silencing vector of Yanofsky et al. by replacing the antisense fragment with an inverted repeat structure according to the teaching of Smith et al. One skilled in the art would have been motivated to do so given the teaching of Smith et al. that the modifications increase the efficiency of gene silencing compared to antisense construct (Figure 1).

Although Yanofsky et al. do not teach a relative weak plant expressible promoter, the Office interprets dehiscence zone specific promoter of Yanofsky et al. to be a relative weak plant expressible promoter according to Applicants' definition of "a relative weak plant expressible promoter" (the specification, paragraph [00042]).

Although Yanofsky et al. do not teach Brassica plant being oilseed rape plant, according paragraph [00054] of the specification, oilseed rape plant includes Brassica

napus, Brassica junceae and Brassica campestris. These three species represent half of six major Brassica species of economic importance (paragraph [0090] of U.S. Patent No. 7,135,621). Therefore oilseed rape plants are regarded as obvious species of Brassica plants.

Although Yanofsky et al. do not teach that the hairpin region formed by the inverted repeat is about 19 or 50 to about 500 or about 200 to about 300 consecutive nucleotides. However, those variants are considered as being obvious design choice.

Although Yanofsky et al. do not teach that an agronomically relevant threshability should be maintained by the pods of transgenic plant, such feature is obviously exhibited by the transgenic plant produced by the modified method.

Thus the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER